8. 510(k) Summary

Date:	31 October 2012
Sponsor:	K7 LLC 54 Moonrise Way Henderson, NV 89074 Phone: 817.219.4441 Facsimile: 817.326.5524
Contact Person:	Michael D. Smith, Manager
Trade Names:	K7C™ Spacer
Device Classification	Class II
Classification Name:	Intervertebral fusion device with bone graft, cervical
Regulation:	888.3080
Device Product Code:	ODP
Device Description:	The K7C™ Spacer is a collection of radiolucent interbody devices having a keystone-shaped cross-section. The superior and inferior surfaces are open with parallel serrations to facilitate implant stability. The implants are available in an assortment of height, length, width and anteroposterior angulation combinations to accommodate a variety of anatomic requirements.
Intended Use:	When used as a cervical intervertebral fusion device, the K7C spacers are indicated for use at one level in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the cervical spine.
Materials:	K7C™ spacers are manufactured from polyetheretherketone (PEEK) per ASTM F2026 (VESTAKEEP® i4 R, Evonik Polymers Technologies GmbH). Integral marker pins are manufactured from tantalum according to ASTM F560.
Predicate Devices:	Eminent Spine (K090064) CenterPulse Spine-Tech (P980048) MC+ (K043479 and K091088) K2M, Inc. (K082698, K101302 and K103169)
Technological Characteristics:	The K7C™ Spacers possess the same technological characteristics as the predicate devices. These include: • intended use (as described above), • basic design (hollow column), • material (polymer), and • sizes (widths, lengths and heights are within the range(s) offered by the predicate systems). Therefore the fundamental scientific technology of the K7C™ Spacers is the same as previously cleared devices.

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Performance Data: Mechanical testing of the worst case K7C™ spacer was performed according to ASTM F2077 and included static and dynamic compression and static and dynamic torsion. The subsidence properties were evaluated according to ASTM F2267.

The mechanical test results demonstrate that the K7C™ Spacers perform as well as or better than the predicate devices. Hence these devices are as safe and as effective as the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 4, 2013

K7, LLC
% BackRoads Consulting, Incorporated
Karen Warden, Ph.D.
Representative/Consultant
P.O. Box 566
Chesterland, Ohio 44026

Re: K123388
Trade/Device Name: K7C™ Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 31, 2012
Received: November 2, 2012

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. Indications for Use Statement

510(k) Number: K123388

Device Name: **K7C™ Spacer**

Indications for Use:

When used as a cervical intervertebral fusion device, the K7C™ spacers are indicated for use at one level in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the cervical spine.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123388